

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

DAVID CHRISTENSON and
ANNIKEN PROSSER,

Plaintiffs,

Case No. 20-cv-194

v.

ALEX AZAR, in his capacity as Secretary
of the United States Department of Health
and Human Services,

Defendant.

DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSES

Defendant Alex Azar, Secretary of the United States Department of Health and Human Services, by its undersigned counsel, hereby answers the plaintiff's complaint as follows:

I. SUMMARY

1. *Tragically, each of the two Plaintiffs is suffering from a particularly deadly form of brain cancer, glioblastoma multiforme (GMB), and they are seeking coverage for life-saving treatment. In a particularly cruel twist, the Secretary is forcing Plaintiffs to prove that they are entitled to the same treatment on a monthly basis, and then the Secretary's decisions differ from month to month with no predictable pattern. The Secretary is playing a game of chance with the Plaintiff's lives; maybe this month they will get life-saving treatment or maybe they won't.*

ANSWER: Admits that plaintiffs have been diagnosed with GMB. Denies the remaining allegations of this paragraph.

2. *The main issue in this case is whether collateral estoppel prevents the Secretary from re-litigating issues already lost in administrative proceedings involving the same parties?*

ANSWER: Denies. The defendant states that under 42 U.S.C. § 405(g), the court's review is limited to whether substantial evidence supports the Secretary's final decision, as set forth in the appealed decisions (ALJ Appeal Numbers 1-8630709341 and 1-8390277469).

3. *The Secretary has asserted that his regulations preclude collateral estoppel and that month-to-month differing decisions on Plaintiff's life-saving care are not arbitrary and capricious even though the facts and/or circumstances have not changed. These positions are wholly without merit under well-established issue preclusion law. U.S. v. Stauffer Chemical Co., 464 U.S. 165 (1984); Astoria Federal Savings & Loan v. Solimino, 501 U.S. 104 (1991).*

ANSWER: Denies.

4. *The other issue is whether it is arbitrary and capricious under basic principles of administrative law for the Secretary to issue conflicting decisions when the facts and/or circumstances have not changed and where the Secretary has determined multiple times that coverage of a medical device to treat Plaintiff's brain cancer was appropriate.*

ANSWER: Denies.

II. JURISDICTION

5. *This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. Each of the Plaintiffs is filing suit after final decisions of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of their Medicare claims (and, therefore, have exhausted their administrative remedies), the amount-in-controversy is more than \$1,630 (42*

U.S.C. §§ 1395ff(b)(1)(E)(i) and 1935ff(b)(1)(E)(iii), and this suit was filed within 60 days of the Secretary's final decisions, as a result of escalation. See 43 C.F.R. § 405.1016(f).

ANSWER: Admits the first sentence. Denies the second sentence, except that the defendant admits plaintiffs meet the amount-in-controversy and that this action was timely filed within 60 days of escalation pursuant to 42 C.F.R. § 405.1132.

6. *Venue is proper in this district pursuant to 42 U.S.C. § 405(g) because this action is being brought in the district of Plaintiffs' residence.*

ANSWER: Admits.

III. PARTIES

7. *Plaintiff David Christenson is an individual and a resident of the State of Wisconsin. Mr. Christenson is eligible for Medicare on the basis of age or disability as previously determined by the Secretary.*

ANSWER: Admits.

8. *Plaintiff Anniken Prosser is an individual and a resident of the State of Wisconsin. Ms. Prosser is eligible for Medicare on the basis of age or disability as previously determined by the Secretary.*

ANSWER: Admits.

9. *Defendant Alex Azar is sued in his official capacity as the Secretary of Health and Human Services.*

ANSWER: Admits.

IV. LEGAL BACKGROUND

10. *The doctrine of mutual collateral estoppel applies to the government and may bar the government from re-litigating facts/issues the government previously litigated and lost. See U.S. v. Stauffer Chemical Co., 464 U.S. 165 (1984).*

ANSWER: Denies.

11. *Moreover, collateral estoppel may be based not only on litigation in federal or state courts but also on proceedings before an agency, when the agency is acting in a judicial capacity. In Astoria Federal Savings & Loan Assoc. v. Solimino, 501 U.S. 104, 107-8 (1991), the Supreme Court held that:*

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact property before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principal of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

ANSWER: Denies.

12. *Numerous courts have applied collateral estoppel to Federal agency decision. Manitowoc Cranes LLC v. Sany America Inc., 2017 WL 6327551,*2 (E.D. Wis. 2017), citing B*

&B Hardware, Inc. v. Hargis Indus., Inc., 135 S. Ct. 1293, 1303 (2015); see, e.g. Brewster v. Barnhard, 145 Fed. App'x 542 (6th Cir. 2005) (SSA ALJ bound by prior determination).

ANSWER: Denies.

V. FACTUAL BACKGROUND

Tumor Treatment Field Therapy (TTFT)

13. *Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically three months. With traditional treatment, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living.*

ANSWER: As to the first sentence of this paragraph, admits that GBM is a type of brain cancer. The defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph.

14. *More recently, a process for treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates.*

ANSWER: Admits that TTFT has been prescribed as treatment in some cases of GBM. The defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph.

15. *In ground-breaking papers published in the Journal of the American Medical Association (JAMA) in 2015 and 2017, TTFT was shown to increase the two-year survival rate by more than 38% and to nearly triple the five-year survival rate.¹*

ANSWER: The defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph. To the extent that plaintiffs are referring to the articles that were submitted as evidence during the administrative review, the defendant refers the court to the certified administrative record at pages 267 through 288 for a complete and accurate statement of their contents.

16. *TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all private insurers cover TTFT. It saves and/or extends GMB patients' lives, in some instances, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It is given a level one recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, i.e., there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.*

ANSWER: The defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph.

17. *The sole supplier of the equipment that delivers Tumor Treatment Field Therapy Novocure, Inc. which manufactures the Optune system. The Optune TTFT system is rented on a*

¹ See Stupp, et al., ‘MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIBLASTOMA; A RANDOMIZED CLINICAL TRIAL”, JAMA, VOL. 314, NO. 23, pgs. 2535-43 (December 15, 2015); Stupp, et al., “EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIBLASTOMA”, JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

monthly basis. Thus, after a patient is prescribed the Optune system, they will have separate monthly claims for Medicare coverage.

ANSWER: Admits that Novocure, Inc. manufactures Optune and that Novocure rents Optune to patients on a monthly basis. The defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph.

18. *Sadly, there is no known cure for GBM and patients prescribed TTFT treatment must continue that treatment for the rest of their hopefully extended lives.*

ANSWER: Denies.

The Medicare Appeals Process

19. *Plaintiffs are enrolled in the medical benefit commonly known as “Original Medicare.” Claims submitted by beneficiaries are subject to a five (5) level appeal process, that can (and typically does) take more than a year. At the first stage, a beneficiary submits a claim. If the claim is denied, the beneficiary can request “redetermination.” If the claim is still denied, the beneficiary can request “reconsideration.” If the claim is still denied, the beneficiary can appeal to an Administrative Law Judge (ALJ). If the ALJ denies the claim, the beneficiary can appeal to the Medicare Appeals Council (MAC). Finally, if the claim is still denied, the beneficiary can file suit in district court.*

ANSWER: Admits plaintiffs are enrolled in Medicare Parts A and B. Defendant denies the remainder of this paragraph and refers the court to 42 C.F.R. § 405.904 for a complete and accurate summary of the levels of administrative review.

20. *While the statutes and regulations require both ALJs and the MAC to issue decisions within 90 days, those deadlines are routinely missed. Thus, beneficiaries seeking coverage are*

often thrown into a multi-year effort to obtain final decisions in their cases before they can seek relief in a federal court.

ANSWER: Denies.

a. Facts Specific to Mr. Christenson

21. *Plaintiff David Christenson has been diagnosed with a GBM and, after receiving other treatment, has been prescribed TTFT.*

ANSWER: Admits.

22. *Mr. Christenson has previously received three favorable decision from ALJs which determined that TTFT is medically reasonable and necessary for him and is a covered benefit. ALJ Appeal Nos. 1-8285652321 (April 2, 2019), 1-8416229632 (June 6, 2019) and 1-8637714249 (September 11, 2019). The Secretary did not appeal any of those decisions and they have become final.*

ANSWER: Denies, except to admit that Mr. Christenson has received three favorable decisions from ALJs: ALJ Appeal 1-8285652321 (April 2, 2019) and combined ALJ Appeal 1-8416229632 and 1-8416270832 (June 6, 2019). The defendant refers the court to the certified administrative record at pages 11 and 23 for complete and accurate copies of these decisions. The defendant further states that he did not appeal these decisions and the decisions are administratively final.

23. *Despite the prior favorable rulings, ALJ Watson issued a decision on September 12, 2019 in ALJ Appeal No. 1-8630709341 holding that TTFT is not medically reasonable and necessary for Mr. Christenson and, therefore, denying coverage.*

ANSWER: Denies. The defendant refers the court to the certified administrative record at page 84 for a complete and accurate copy of this decision.

24. *Mr. Christenson timely appealed ALJ Watson's decision on September 18, 2019. When no decision was received within 90 days, Mr. Christenson filed a notice of escalation pursuant to 42 C.F.R. § 405.1016(f) on January 3, 2020.*

ANSWER: As to the first sentence of this paragraph, admits. As to the second sentence of this paragraph, denies. The defendant further states that the escalation was pursuant to 42 C.F.R. § 405.1132.

25. *On January 22, 2020, the Medicare Appeals Council (MAC) responded indicating that they could not timely issue a decision and that judicial review was authorized within 60 days of the letter.*

ANSWER: Admits. The defendant refers the court to the certified administrative record at page 57 for complete and accurate copies of the MAC's letter.

26. *Accordingly, Mr. Christenson is entitled to a judicial review.*

ANSWER: Admits.

b. Facts Specific to Ms. Prosser

27. *Plaintiff Anniken Prosser has been diagnosed with a GBM and, after receiving other treatment, has been prescribed TTFT.*

ANSWER: Admits.

28. *Ms. Prosser has previously received a favorable ALJ decision determining that TTFT is medically reasonable and necessary for her and is a covered benefit. ALJ Appeal No. 1-84161888648. The Secretary did not appeal that decision and it has become final.*

ANSWER: Denies, except to admit that Ms. Prosser has received a favorable decision from an ALJ in ALJ Appeal Number 1-84161888648. The defendant refers the court to the certified administrative record at page 4354 for a complete and accurate copy of this decision. The defendant further states that he did not appeal this decision and it is administratively final.

29. *Despite the prior favorable, ALJ Grow issued a decision on June 19, 2019 in ALJ Appeal No. 1-8390277469 holding that TTFT is not medically reasonable and necessary for Ms. Prosser and, therefore, denying coverage.*

ANSWER: Denies. The defendant refers the court to the certified administrative record at page 4380 for a complete and accurate copy of this decision.

30. *Ms. Prosser timely appealed ALJ Grow's decision on July 12, 2019. When no decision was received within 90 days, Ms. Prosser filed a notice of escalation on January 2, 2020 pursuant to 42 C.F.R. § 405.10106(f). No response has been received to date.*

ANSWER: As to the first sentence of this paragraph, admits. As to the second sentence of this paragraph, denies. The defendant further states that the escalation was pursuant to 42 C.F.R. § 405.1132. As to the third sentence of this paragraph, denies. The defendant refers the court to the certified administrative record at page 4332 for a complete and accurate copy of the Appeals Council's January 22, 2019 response.

31. *On January 22, 2020, the Medicare Appeals Council (MAC) responded indicating that they could not timely issue a decision and that judicial review was authorized within 60 days of the letter.*

ANSWER: Admits. The defendant refers the court to the certified administrative record at page 4332 for complete and accurate copy of the MAC's letter.

32. Accordingly, Ms. Prosser is entitled to judicial review.

ANSWER: Admits.

VI. LEGAL CAUSES OF ACTION

COUNT I

Violation of 42 U.S.C. §405(g)

(contrary to law)

33. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as contrary to law, as arbitrary and capricious, an abuse of discretion, and unsupported by the evidence, and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

ANSWER: Denies.

COUNT II

Violation of 5 U.S.C. § 706(1)

(unlawfully withheld or unreasonably delayed)

34. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

ANSWER: Denies.

COUNT III

Violation of 5 U.S.C. § 706(2)(A)

(arbitrary and capricious, abuse of discretion, not in accordance with law)

35. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance

with the law, and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

ANSWER: Denies.

COUNT IV

Violation of 5 U.S.C. § 706(2)(C)

(in excess of statutory jurisdiction, authority, or limitations or short of statutory right)

36. *Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as in excess of the Secretary's authority and limitations and short of Plaintiffs' statutory rights and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.*

ANSWER: Denies.

COUNT V

Violation of 5 U.S.C. § 706(2)(D)

(without observance of procedure required by law)

37. *Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as done without observance of the procedure required by law and issue an order finding that Plaintiff's claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.*

ANSWER: Denies.

COUNT VI

Violation of 5 U.S.C. § 706(2)(E)

(not supported by substantial evidence)

38. *Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as not supported by substantial evidence and issue an order finding that Plaintiff's*

claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

ANSWER: Denies.

VII. REQUEST FOR DECLARATORY JUDGMENT

39. *It is appropriate to declare the rights and legal relations of both plaintiffs regarding payment of the past and future monthly claims for Tumor Treatment Field Therapy by the Medicare program.*

ANSWER: Denies.

VIII. JURY DEMAND

40. PLAINTIFFS DEMAND A JURY TRIAL.

ANSWER: Plaintiffs are not entitled to a jury trial.

Defendant denies that plaintiffs are entitled to the relief sought.

The defendant denies all allegations in the Complaint not specifically admitted or denied.

IX. AFFIRMATIVE DEFENSES

1. The complaint fails to state a claim upon which relief can be granted.

2. Collateral estoppel does not apply to non-precedential decisions issued by Administrative Law Judges.

3. ALJ Appeal Nos. 1-8630709341 and 1-8390277469 are supported by substantial evidence.

Defendant has, or may have, additional affirmative defenses that are not known at this time.

Defendant specifically reserves those and other affirmative defenses.

For the reasons set forth above, the Court should affirm the final agency decisions, dismiss all claims against the defendant, and deny all claims for relief asserted by the plaintiffs.

Dated at Milwaukee, Wisconsin this 20th day of April, 2020.

Respectfully submitted,

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By: /s/ Chris R. Larsen

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